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EXAMINER
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ART UNIT	PAPER NUMBER
1634	27

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/341,227	DURR ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Response to Amendment

2. On 06 May 2002 an amendment to the subject application was received. The amendment requested *inter alia,* that page 13 be replaced with new replacement page 13. A review of the amendment failed to locate the replacement page. Accordingly, the amendment to page 13 has not been effected and the objection to the specification as it relates to the presence of trademarks remains in effect.

Drawings

3. On 21 March 2000 the Office mailed an Office action, Paper No. 8, wherein was attached a Form PTO-948 where certain objections to the drawings were made by the Draftsperson. Effective 03 May 2001 the correction of drawings may not be held in abeyance. Accordingly, corrected drawings are required to be filed in response to the instant Office action. Please note below information pertaining to how to effect drawing changes.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is noted with particularity that there are claims drawn to two distinct inventions: one a method for isolating macromolecules and the other being a device. The title introduced via the amendment of 06 May 2002, having a Certificate of Mailing date of 30 April 2002, does not address this second group of clams (see claims 18, 19, and 24).

5. The use of the trademark NONIDET P-40 (NP-40) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

6. Claims 20-23 and 26-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of claims 20-23 and 26-28 depend from claim 13. The method of claim 13 explicitly requires the isolation of macromolecules on a membrane in a microchannel. In contrast, the method of claim 20 recites the use of a "capillary." Claims 21-23, which depend from said claim 20, and ultimately from said claim 13, fail t overcome this issue and are similarly objected to. Claim 25 recites the collection of the macromolecules on a membrane located in a "channel," not a microchannel. The use of a "channel" is considered to broaden the scope of the method over that of where a "microchannel" is required. Claims 25-28, which depend from said claim 25, and which ultimately depend from claim 13, fail to overcome this issue and are similarly objected to.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See pages 2-9 of the prior Office action for the basis of the rejection.

Response to argument

Acknowledgement is made of applicant's argument where at pages 5-7 it is asserted that the claimed invention is fully enabled by the specification. At page 8, and again at page 10 it is asserted that the claimed method does not relate to any chemical reaction, or physiology. At page 8, last paragraph, it is asserted:

> The invention does not require any starting materials, intermediates or products, as these terms are used in chemistry. The macromolecules as used herein do not catalyze reactions, nor are they converted during their isolation to other molecular species - they are merely being separated in a highly sensitive and novel manner. (Emphasis in the original.)

At page 10 applicants assert:

> There is absolutely no reasonable basis to conclude that Applicants' method encompasses "any one or combination of analytical methods on virtually [any] compound or composition of matter."
>
> The preamble of the amended claim clearly indicates that the invention as described is a method that is largely directed to the isolation of macromolecules. The invention is not directed to specific analyses, as the Examiner seems to suggest. A claim limitation reciting "thereafter analyzing the macromolecules" is clearly within the scope of the claims. This is because one of skill in the art would know what analyses can be performed on filter-concentrated specimens, and thus would know when using the

> method is appropriate. The claims clearly do not cover virtually any analytic method, and the Examiner has improperly read this limitation into the claim. The limitation is merely the act of analyzing the isolated macromolecule according to methods known in the art. (Emphasis in the original.)

9. The above arguments have been fully considered and have not been found persuasive towards the withdrawal of the rejection of claims under 35 USC 112, first paragraph. Contrary to applicant's arguments at page 8, yet partial agreement is found with the argument found at page 10 of the response, independent claim 13, the claim from which claims 14-28 depend, requires "analyzing the macromolecules." Absent a limitation to the contrary, the claims are read as broadly as is reasonably possible. Such 'analysis", without more, is fairly considered to encompass virtually any and all means of analysis. Indeed, applicant at page 10 of their response seemingly finds themselves in agreement with this position where they state that the claims encompass "methods known in the art." Such methods, in the absence of evidence to the contrary, are considered to encompass virtually any known chemical and biochemical reactions as well as those that simulate physiological reactions.

10. While applicant asserted that the claimed method "does not require any starting materials, intermediates or products," and emphatically asserts that the invention "is not directed to specific analyses" (emphasis in the original) it is noted that claim 16, which further limits claim 13, specifically recites that the method comprises "subjecting the macromolecules to MS, gel electrophoresis, PCR, TEM, nucleic acid sequencing, immunodiagnosis or hybridization." Not only are these explicitly recited forms of specific types of analysis to be performed, but they also require a starting material and, in the case of at least PCR and sequencing, encompass the use of enzymes, the production of intermediates as well as final products.

11. At page 8 of the response it is asserted:

> **There is nothing in the specification that connects the invention to any physiological process or measurement thereof.** The invention relates to isolating macromolecules including intact viruses or bacteria based on their sizes, shapes and net charges. ***There is not even one connection, suggestion or teaching to link the invention to physiology***. (Emphasis in the original.)

Yet at page 11 applicant is in agreement that viruses, microbes, and fungi (limitations of claims 14 and 29) are life forms. Applicant assertion that "the claimed invention works just as well if the microbes were dead" is taken as meaning that the invention works as well as when they are dead or alive. Clearly, there is no limitation that the viruses, bacteria or fungi are dead (see claims 14 and 29). Accordingly, the claims have been read as broadly as is reasonably possible, and such breadth encompasses the isolation and analysis of life forms where undoubtedly physiological systems will be present. As presented in the prior Office action, chemical and physiological reactions/systems are recognized (*Fisher*) as being inherently unpredictable and require greater levels of disclosure.

12. At page 5 of the response applicant asserts that the examiner has provided only "an unsupported conclusory statement" that the claims are not enabled by the specification yet, at page 13 applicant acknowledges, "the Examiner has indicated some of the variables to consider in practicing the invention." Such statements at page 13 seem to be in stark contrast to the assertions at page 5.

13. At page 10 of the response argument is presented in that the breadth of the claims has been improperly interpreted, taking exception to the aspect of the claims encompassing "any composition of matter, organic in nature or otherwise." It is noted, however, that applicants do not assert just what the claims do cover. Upon inspection of claim 13, it is noted that the claim

recites generally that one is to isolate and subsequently analyze "macromolecules" on a membrane. No restriction is placed on just what type(s) of macromolecules are to be encompassed. Dependent claim 14 specifically recites that the "macromolecules are selected from nucleic acids, viruses, proteins, bacteria, or fungi." Recognizing that a dependent claim must further limit the scope of a claim from which it depends, claim 13 is considered to encompass not only these admitted life forms, but additional macromolecules as well. With Claim 13 not placing any restriction on the type of "macromolecule," and seeing that the macromolecule clearly encompasses life forms as well as other macromolecules, such breadth has been interpreted as broadly as is reasonably possible. Accordingly, and in the absence of convincing evidence to the contrary, the claims, e.g., claim 13, continue to be interpreted as encompassing virtually any macromolecule, including life forms.

14. At page 11, bridging to page 12, it is asserted that "there is no foreseeable value in a capillary that is not translucent and thus, amenable to analysis by UV. Further, there are ample teachings relating to the structure of the apparatus. These teachings are sufficient, to enable one with ordinary skill in the art to practice the invention." Applicants direct attention various portions of the specification.

15. The above argument has been fully considered and has not been found persuasive. While the specification may urge one to use one embodiment over that of another, such limitations are not read into the claims. The specification must enable the full scope of the claims, not just that portion which applicant considers "foreseeable." Where the claims encompass what applicant considers "foreseeable" as well as "unforeseeable," the specification needs to fully enable both.

Absent such full and complete enablement, narrowing of the claims scope to where it more nearly mirrors the enablement provided is in order.

16. Agreement is reached with applicant to the extent that, at page 24 of the disclosure, there is found an example directed to the isolation and study of HSV-2 via negative stain electron microscopy. Said example, however, has not been found to be sufficient to fully enable the complete scope of the claimed invention.

17. At page 14 applicant assert, in response to concern raised by the Office that the disclosure does not set forth a reproducible method whereby any membrane can be inserted into a microchannel, asserts that the claimed device and related method can be practiced where "the device is … separable into two parts, which are reassembled with a porous membrane in between;" attention being directed to Figures 6 and 7.

18. Applicant's argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection, as the claimed method and device are not limited to where the device is comprised of two parts. Further, the claims do not recite that a membrane is inserted between two segments. Rather, the claims require that the membrane be placed "in a microchannel" (claim 13; emphasis added). Placing a membrane between two blocks that comprise microchannels, such that the membrane is located between two discontinuous segments of a microchannel is not considered to satisfy the requirement that the membrane is "in the microchannel." Furthermore, the membrane depicted in Figures 6 and 7 extends well beyond the lumen of the channels, and seemingly is as broad as the entire block/substrate that comprises the microchannels. Such all-spanning membrane is not considered to be "in the microchannel."

Again, limitations found in applicant's specification and in their arguments are not read into the claims.

19. At page 15 of the response argument is presented in response to where at page 7, first full paragraph of the prior Office action it is asserted:

> The method and device claims do not recite any means or steps whereby the result of any analytical method is detected and correlated with any results obtained.

Applicant directs attention to pages 22-25 of the disclosure as showing that DNA can be concentrated and that HSV was labeled and studied via electron microscopy.

20. While the specification may disclose certain methodologies, the claims do not recite that any method step needs to be preformed in order to achieve the requisite "analyzing." In support of this position, it is noted that claim 13 simply calls for "analyzing the macromolecules collected" and claim 17 indicates that one is to "analyze the nucleic acids collected without amplifying the nucleic acids." As presently worded, the claims encompass a method of analysis where no positive active step of analysis it to be performed. The specification does not enable a method of analysis of any macromolecule where no active method step of analysis is performed. While applicant has directed attention to portions of the specification where active method steps were performed so to achieve the requisite analysis, such limitations are not read into the claims.

21. Claims 18, 19, and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to set forth in sufficient detail a device that permits any form of analysis of any and all possible "macromolecules." As set forth

in claim 18, the device is to comprise a "chip module" and from 1 to 400 capillaries with an embedded membrane. The specification does not provide an adequate written description of a device, or methods for its manufacture and use. As presently claimed, the device does not have any means for introducing the sample, for processing the sample, or for the removal of any macromolecules that have been collected on the membrane, even though claim 13 positively recites that the method requires that the device allow for removing the macromolecules "by applying a pressure gradient or voltage across said membrane." As a result of the deficiencies of the specification in describing the claimed device in sufficient detail, the subject application has not been found to reasonably suggest that applicant was in possession of the full scope of devices being claimed.

22. It is further noted that the device of claim 24 defines the device as "comprising a channel adapted to analyze salt-containing samples with embedded membrane." The aspect of defining the channel not in terms of what it is, but rather in terms of how it is to function under some unspecified conditions, does constitute an adequate written description of the channel or of the invention.

Response to argument

23. At pages 18-19 of the response received 06 May 2002 argument is presented that the claims have been improperly interpreted. Argument is advanced that "the invention [specification] does not suggest anywhere that it can be used for 'any form of analysis.'"

Applicant also asserts:

> "...using any non-claimed sample preparation in conjunction with a particular standard analysis does not read on claim 13 because the claimed invention has not been used. The Applicants are not incorporating the universe of specific analyses as claim limitations,

> therefore it is improper to require that the specification adequately disclose all analyses and potential uses of the invention." (Emphasis in the original.)

24. The above argument has been fully considered and has not been found persuasive. It is noted with particularity that the instant rejection of claims 18, 19, and 24 is under the written description portion/requirement of 35 USC 112, first paragraph. It is well settled that the specification must describe the invention in "in such full, clear, concise, and exact terms" not only to enable its use, but to allow the public to recognize just what is being claimed and to reasonably suggest that applicant was in possession of the invention at the time of filing. In support of this position, attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

As presently worded, claims 18, 19, and 24 encompass a device that is to be used in the method of claim 13 and is to comprise from "1 to 400 capillaries with embedded membrane." While claim 19 defines the material that the device is to be comprised of, it is noted that claim 24 requires that the membrane-embedded channels are to be "adapted to analyzed salt-containing samples." As presented above, the method of claim 13 has been interpreted as encompassing the analysis of any and all macromolecules. Accordingly, the claimed device is considered to allow for, at a minimum, the collection and analysis of this unlimited variety of samples and their macromolecules. The claims do not place any limitation on the diameter of the microchannels or

on their length. The specification does not support the position that applicant was in possession of any and all manner of microchannel devices. Page 6 of the disclosure states:

"The microchannel has an internal diameter of 10-100 μm and a total length of 3-50 cm." Page 8 of the disclosure further indicates that the "entire module is thus 3 to 10 cm long, 1 to 50 mm wide and 0.1 to 50 mm thick." Clearly, the recitation of specific diameters and lengths does not support the position that applicant was in possession of alternative embodiments. Similarly, the same page of the specification clearly states that the membrane is to have a pore size that ranges from a 3000 MW cut off to with an upper pore size limit of 0.45 mm. Again, the specification does not provide an adequate written description of a device that comprises a membrane of any and all manner of pore sizes, but rather, a definitive range of pore sizes. While applicant has presented argument that it is improper to read the claim as encompassing embodiments not specifically recited or claimed, such an argument has not been found persuasive as the claims are to be read as broadly as is reasonably possible. In support of this position, attention is directed to MPEP 2111.01, reproduced in pertinent part *infra*:

> THE WORDS OF A CLAIM MUST BE GIVEN THEIR "PLAIN MEANING" UNLESS THEY ARE DEFINED IN THE SPECIFICATION
>
> While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below). One must bear in mind that, especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification. It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). There is one exception, and that is when an element is claimed using language falling under the scope of 35 U.S.C. 112, 6th paragraph (often broadly referred to as means or step plus function language). In that case, the specification must be consulted to determine the

> structure, material, or acts corresponding to the function recited in the claim. In re Donaldson, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see MPEP § 2181-§ 2186). (Emphasis added)

It is further noted that the device of claim 18 is explicitly required to be "adapted to perform the method of claim 13." The method of claim 13 requires not only "electrokinetically collecting macromolecules on a membrane" but also the analysis of same. The method of claim 13 does not require that the membrane or the macromolecules be removed from the microchannel. In deed, amended claim 13 requires, in at least one embodiment, "collecting macromolecules on a membrane in a microchannel and thereafter analyzing the macromolecules . . . on said membrane." Accordingly, the claimed device has been interpreted as allowing for the analysis to be performed whilst the membrane and collected macromolecules are within the microchannel(s) where, in keeping with claim 18, said device can comprise 400 such microchannels. As presented in the prior Office action, the claimed device does not recite such essential elements as means for analysis, or even means whereby one would be able to electrokinetically collect any macromolecule on a membrane embedded within the microchannel.

25. As for applicant's argument that the aspect of analysis have been interpreted overly broad, it is noted that at page 8 of the disclosure, applicant explicitly states that the macromolecules "can be further analysed by all conceivable methods." Clearly, to assert that the claims encompass virtually any means of analysis is not unreasonable.

26. Upon review of the disclosure it is apparent that the device does not have or comprise a membrane that is truly embedded in the microchannels, but rather, the membrane is "clamped between module blocks" (specification at page 8, last paragraph). While Figure 1 may well depict a membrane within a channel, the disclosure does not set forth in sufficient detail just how

one is to make a device that has as a membrane "internal" or "embedded" to a microchannel. Similarly, the specification has not been found to adequately describe a device that is to allow for electrokinetic separation of any macromolecule when it is not in electrical connection with any power source; claims 18, 19, and 24 do not require any electrical connection, pumping means so that a pressure gradient could be applied in the method of claim 13. Again, applicant is urged to consider amending the clams so that all essential elements are recited in the device claims such that the methods of analysis of claim 13 can be practiced.

27. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 13-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

30. Claims 13-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. A review of the claims finds a characterization in some instances of where the device used in the collection and at analysis of the collection macromolecule. The method of "analyzing" by "analyzing" does not adequately describe the method steps needed to practice the claimed method. Claims 18, 19, and 24, drawn to a device to be used in the method, do not overcome this issue and are similarly rejected.

Response to argument

At page 21 of the response received 06 May 2002 it is stated:

> It is important to note that the claims do not seek to cover the analysis methods *per se*, and thus Applicant need not include the steps in the subsequent analyses. What is covered is the isolation of a macromolecule that is to be analyzed.
>
> Although the Examiner believes this too broad, the Applicant reiterate that no specific analyses by themselves are covered.

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. While applicant has clearly indicated that they do not intend to claim methods of analyses, such scope of fairly encompassed by the claims. Such claim interpretation is in no small way due to the explicit recitation that an analysis is to be performed. As for performing specific types of analyses, claim 16 explicitly states the method of claim 13 further comprises the performance of "MS, gel electrophoresis, PCR, TEM, nucleic acid sequencing, immunodiagnosis or hybridization." If applicant wishes to claim a method of collecting macromolecules on a membrane, then it is urged that the claims be amended so to reflect that the claims are to be drawn just to this embodiment.

31. Claims 20-23 and 25-28 are indefinite with respect to what constitutes a "capillary" or a "channel" and how these embodiments are to be related to the "microchannel" set forth in claim 13. Claims 21-23, which depend from said claim 20; and claims 24-28, which depend from said claim 25, fail to overcome this issue and are similarly rejected.

32. Claims 24-28 are confusing as to how the microchannel relates to the channel and how the membrane in the microchannel relates to the membrane that is in a "channel." In claim 13 a membrane is "in a microchannel." In claim 25, however, it is now recited that the membrane is

in "a channel adapted to analyse salt-containing samples." It is not clear ho these embodiments relate to one another.

Claim Rejections - 35 USC § 102/103

33. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

34. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

36. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

37. Claims 13-23 and 29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Naylor et al. (US Patent 5,800,692).

38. Naylor discloses a capillary device that comprises one or more membranes is used in methods for the concentration and analysis of macromolecules. At column 8 Naylor defines "sample processing material" as a "membrane" (column 8, lines 31-32). Column 8, penultimate paragraph, discloses that the capillary device can take on any of a variety of formats. Column 8, last paragraph, teaches that "[t]he sample processing material [membrane] can be used to concentrate, wash, or otherwise process a sample prior to **or during, electrophoretic separation**." (Emphasis added.) Columns 9 and 10 describe a plethora of membrane materials and arrangements. Means for introducing the sample into the microbore capillary are disclosed in column 10. Means of detection are disclosed at column 13. Specific reference to application of electrokinetic force and bringing the charged sample components into contact with the membrane are disclosed in column 13.

39. Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naylor et al., in view of Wu et al. (US Patent 5,985,121).

40. Naylor discloses a capillary device that comprises one or more membranes is used in methods for the concentration and analysis of macromolecules. At column 8 Naylor defines

"sample processing material" as a "membrane" (column 8, lines 31-32). Column 8, penultimate paragraph, discloses that the capillary device can take on any of a variety of formats. Column 8, last paragraph, teaches that "[t]he sample processing material [membrane] can be used to concentrate, wash, or otherwise process a sample prior to **or during, electrophoretic separation**." (Emphasis added.) Columns 9 and 10 describe a plethora of membrane materials and arrangements. Means for introducing the sample into the microbore capillary are disclosed in column 10. Means of detection are disclosed at column 13. Specific reference to application of electrokinetic force and bringing the charged sample components into contact with the membrane are disclosed in column 13.

41. Naylor et al., do not teach explicitly of their device being used in buffers having a salt.

42. Wu et al., teach performing capillary electrophoresis where the device has been adapted so to compensate for samples that have a high salt concentration.

43. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have modified the device and protocols of Naylor et al., such that it would be useful in the analysis of macromolecules that are found in salt-containing samples. In view of the increased capacity to study both salt-containing and salt free samples, the ordinary artisan would have been motivated to effect this modification. Also, said ordinary artisan would have had a reasonable expectation in view of the detailed guidance provided by both Wu et al., and Naylor et al.

44. For the abode reasons, and in the absence of convincing evidence to the contrary, the claimed invention is anticipated, if not rendered obvious by the prior art of record.

Conclusion

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

47. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 14, 2002